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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,313	05/14/2001	Terry B. Strom	01948-056001	8786

7590 10/01/2002

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/855,313</b>	Applicant(s) <b>Strom et al</b>
	Examiner <b>Fozia Hamud</b>	Art Unit <b>1647</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on Apr 11, 2002
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-42 are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, 13-17, drawn to a therapeutic composition comprising a first agent and a second agent, wherein the first agent is a mutant of IL-15, wherein the second agent is anti-B7 antibody, classified in class 424, subclass 85.2.
  - II. Claim 1, 12, drawn to a therapeutic composition comprising a first agent and a second agent, wherein the first agent is an anti-IL15R antibody, classified in class 424, subclass 145.1.
  - III. Claims 1-11, 18-19, drawn to a therapeutic composition comprising a first agent, wherein the first agent is a mutant of IL-15, and the second agent is anti- CD28 antibody, classified in class 424, subclass 143.1.
  - IV. Claims 1-11, 20-23, drawn to a therapeutic composition comprising a first agent, wherein the first agent is a mutant of IL-15, and the second agent is anti-CD40L antibody or anti- CD40 antibody, classified in class 424, subclass 145.1.
  - V. Claims 24-37, drawn to a method of suppressing an immune response by administering a therapeutic composition comprising a first agent and a second agent, classified in class 512, subclass 885.
  - VI. Claims 38-40, drawn to a method of eliminating a cell that expresses a receptor for IL-15, by exposing said cell to therapeutic composition comprising a first agent and a second agent, classified in class 435, subclass 7.2.

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VII. Claim 41, drawn to a method of diagnosing a patient, by exposing a sample to an antigenically tagged IL-15 R polypeptide, classified in class 424, subclass 9.1.

VIII. Claim 42, drawn to a method of making a therapeutic composition comprising mutant IL-15 polypeptide, by purifying the mutant from an expression system, classified in class 530, subclass 413.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent use, that is distinct for each invention which cannot be exchanged. The therapeutics agents of Groups I-V target different signaling pathways of the immune system, for example, a therapeutic agent that comprise a mutant of IL-15 and an anti-body to B-7 blocks B7 signaling pathway, while a therapeutic agent that comprises an IL-15 mutant and anti-CD40 antibody blocks CD40L/CD40 signaling pathway.

Inventions I-V and VI are related as products and process of use. However, the inventions are distinct because the therapeutic agents of Groups I -V as claimed can be used in materially different methods, such as it can be used diagnostically.

Inventions I-V and VII are related as products and process of use. However, the inventions are distinct because the therapeutic agents of Groups I -V as claimed can be used in materially different methods, such as it can be used therapeutically.

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Inventions VI-VIII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different goals. The methods are distinct because each assay is performed for divergent purposes.

Inventions I-V are unrelated to inventions VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group VIII, neither uses nor produces none of the products of Groups I-V.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
30 September 2002

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER